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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thomas Zelinski

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,427	ZELINSKI ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-16 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-16, 20, 21 and 27-30 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/09/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 14-16, 18-30 are pending.

Election/Restrictions

Applicant's election of Group I, claims 14-21, the specie *Alcaligenes* and fine chemicals is again acknowledged. Claim 23 should have the status identifier of "withdrawn".

Claims 14-16, 18, 20, 21 and 27-30 are under examination.

Claims 19 and 22-26 stand withdrawn.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 12/09/2009. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 21 and 27 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the last Office action and as given herein.

Claims 21 and 27 were rejected because it is confusing as to what is meant by adding ionic solutions in an aqueous environment which is outside the microorganism whereas the nitrilase activity in the form of an enzyme is apparently inside the microorganism.

Applicant asserts that the claims have been amended to provide further clarification to overcome the rejection.

The rejection stands because the parts of the claims to which the rejection refers have not been amended to provide further clarification as alleged.

Claim Rejections - 35 USC § 103

Claims 14-16, 20, 29 and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chibata et al. (US 3,898,128; Chibata '128) in view of Chibata et al. (US 4,526,867; Chibata '867) and Sigma Catalog (1998) for the reasons stated in the last Office action and as given herein.

Applicant argues that the treatment with glutaraldehyde is for a short period (1 minute to 24 hours) of time prior to immobilization of the cells. Applicant argues that because glutaraldehyde is removed prior to the additional steps for immobilization, the cells are stored without the presence of glutaraldehyde and that the disclosed series of steps does not teach or suggest "preserving" or "storing".

Applicant argues that the method of Chibata II ('867) is directed to preparing an immobilized microorganism having higher stability and higher enzymatic activity for a long period of time in a continuous enzymatic reaction and the purpose of the glutaraldehyde is for stabilization of enzymatic activity. Applicant asserts that the

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present invention is directed to preserving and/or storing a microorganism in an aqueous medium comprising an aldehyde prior to enzymatic reaction and that Chibata II ('867) does not teach or suggest the use of an aqueous medium for preserving and/or storing a microorganism prior to an enzymatic reaction.

Applicant argues that Chibata II ("867) teaches away from including an aldehyde in an aqueous medium for preserving and/or storing a microorganism because the glutaraldehyde is removed after the brief treatment and prior to the additional steps for immobilization. Applicant concludes that the *A. faecalis* cells would not have been preserved or stored in an aqueous medium comprising an aldehyde as required by the claims since the references motivate one to remove glutaraldehyde from the cell prior to immobilization.

Applicant submits that the skilled artisan would not have had a reasonable expectation of preserving the nitrilase activity for a period up to 37 days from the combined references.

Applicant's arguments have been considered but they are not persuasive.

Responding to Applicant's arguments that the cells are subjected to glutaraldehyde for a "short" period of time, that the glutaraldehyde is removed prior to immobilization, that Chibata is directed to optimization of an enzymatic reaction and that the references do not teach preserving and/or storing, Chibata practices the claimed steps: *Alcaligenese* cells are contacted with glutaraldehyde in an aqueous medium. Hence, they are naturally stored and preserved by said aldehyde before they are contacted with the polysaccharide to entrap the cells. The step of immobilization is not

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relevant since the combined disclosures teach the steps of the presently claimed method: contacting cells with an aldehyde at a concentration that overlaps that which is claimed (at 0.1 M (100 mM)). The initial contacting step of the cultivated cells with glutaraldehyde meets the limitation of an aqueous medium since the cells are in a culture broth and glutaraldehyde is supplied as a wt. % in water (Sigma catalog page 536). The claim does not specify how long the medium is an aqueous medium. Thus, the glutaraldehyde is in an aqueous medium until all of it is used up for the immobilization process. The cells are stored and preserved by said aldehyde before they are contacted with the polysaccharide to entrap the cells.

Regarding Applicant's argument that Chibata teaches away from including an aldehyde in an aqueous medium for the purpose of preserving and/or storing a microorganism, Chibata practices the step of contacting the cells with an aqueous medium comprising glutaraldehyde. That the glutaraldehyde is removed prior to immobilization is immaterial since Chibata teaches the claimed step.

Responding to Applicant's arguments regarding the preservation of nitrilase activity for a period up to 37 days, the range of the time of the contacting step taught by Chibata (1 minute to 24 hours or 5 minutes to 5 hours) meets the limitation of preservation for up to 37 days since the range overlaps with the claimed range. The time that the cells are in contact with the glutaraldehyde is regarded as storage time.

The preservation of the activity for up to 37 days follows since the combined references teach the contacting step of cells with glutaraldehyde at the claimed concentration. Applicant has not met the burden that proves otherwise.

Claim 28 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Chibata et al. (US 3,898,128; Chibata '128) in view of Chibata et al. (US 4,526,867; Chibata '867) and Sigma Catalog (1998) in further view of Choi et al. (US 6,649,382) for the reasons stated in the last Office action and the reasons given herein.

Applicant asserts that the combination of the two Chibata references does not render the main claim obvious and that the combination of the Chibata references and Sigma catalog with Choi to not render claim 28 obvious.

Applicant's argument has been considered but it is not persuasive. The combination of the Chibata references with Sigma catalog meets the claimed limitations because the combined references teach the step of contacting cells with an aqueous medium comprising an aldehyde. Hence, they are naturally stored and preserved by said aldehyde before they are contacted with the polysaccharide to entrap the cells.

Choi was relied upon show that the use of recombinant *Alcaligenes* was known at the time of the instant invention and that they would function in substantially the same manner as their non-recombinant counterparts.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651